

***Prophylactic Oophorectomy at the time of
hysterectomy for benign disease: current
practice and need for guidelines***

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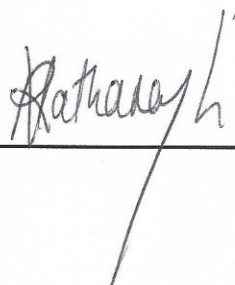
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Dedication and Acknowledgements

- I would like to thank almighty GOD for giving me the strength and direction I needed to complete my study.
- Thank you to my family for their kind words of support and assistance, without which this study would not have been possible.
- To Dr R Gangaram thank you for your counsel and advice, I am eternally grateful for your support.
- Finally I would like to dedicate this study to my husband and children, you are my inspiration and my reason for succeeding.

I, Dr Rochelle Vatharajh do hereby declare that the work on which this dissertation is based on is my original work, under the supervision and mentorship of Dr R Gangaram. This dissertation has not been previously submitted to any other colleges.





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GLOSSARY

BSO	Bilateral salpingo-oophorectomy
FSH	Follicle stimulating hormone
LH	Luteinising hormone
HDL	High density lipoproteins
WHI	Women's Health Initiative
CEE	Combined equine oestrogen
ACOG	American college of Obstetrics and Gynaecology
RCOG	Royal College of Obstetrics and Gynaecology
RANZOG	Royal Australian and New Zealand College of Obstetrics and Gynaecology
HRT	Hormone replacement therapy
CAD	Coronary artery disease
PO	Prophylactic oophorectomy
DVT	Deep vein thrombosis

ABSTRACT

OBJECTIVES

1. To identify local practice of prophylactic oophorectomy at the time of hysterectomy.
2. To identify which conditions would favour ovarian preservation versus those conditions that would support oophorectomy.
3. To identify which guidelines gynaecologists, registrars and medical officers practice.
4. To assess the need for local guidelines on prophylactic oophorectomy when it is performed at the time of hysterectomy for benign disease.
5. To assess if differences in practices exist between different groups (public, private consultants, senior registrars, medical officers, male and females).

METHODOLOGY

A comprehensive literature search was made using internet facilities namely PubMed, Medline sources as well as recent articles in the University of KwaZulu Natal library. An anonymous structured questionnaire was drawn up. The questionnaire (Appendix C) analysed age, gender, years of experience and whether prophylactic oophorectomy was opposed or proposed and which guidelines doctors used. The questionnaire also asked if there was a need for local guidelines. A statistician was consulted to calculate the relevant sample required. Ethical approval (Appendix A) was obtained from the ethics committee of the University of KwaZulu Natal. The questionnaire was distributed at the SASOG (South African Society for Obstetricians and Gynaecologists) 2012 conference. This is a national meeting attended by gynaecologists, registrars and medical - officers interested in obstetrics and gynaecology. Permission was first sort from the SASOG chairman prior to distribution of the questionnaire at the conference. At this meeting the questionnaire was distributed to all delegates to complete. SPSS version 19 was used to analyse the data.

RESULTS

One hundred and eighty five participants took part in this questionnaire based study. The mean (range) age of the participants was 46 ± 8.2 (range: 28-75) years. The participants included specialists (n=147), registrars (n=35) and medical officers (n=3). The mean (SD) age of the specialists was 47.9 ± 14.2 years and the mean (range) number of months since being qualified as a specialist was 16 (1-146) months The mean (SD) age of the registrars

was 51.6 ± 14.7 years and the mean (range) number of years in training 3 (1-5) years. The mean (SD) age of the medical officers was 48.3 ± 2.9 years. There was no difference in age between the participants ($p=0.3$). The age groups of the participants were as follows: 20-30 ($n=6$; 3%); 31- 40 ($n= 60$; 32%); 41-50 ($n=58$; 31%); 51-60 ($n=42$; 23%) and >60 ($n=19$; 10%). One hundred and twelve (71%) of participants were male and the remaining 73 (39%) were females. Eighty eight (48%) were practicing in private, 71 (38%) were practicing in the public sector while 36 (14%) were practicing in both private and public sector.

Among the participants there were 147 (79%) specialists, 35 (19%) registrars and 3 (2%) were medical officers. The mean (SD + range) age at which specialists, registrars and medical officers recommend patients to have prophylactic oophorectomy following hysterectomy for benign conditions was 52.18 ± 4.7 (35-65); 54.49 ± 5.3 and 55 ± 3.9 years respectively. There was no difference between specialists, registrars and medical officers with regards to age at which they recommend patients to have prophylactic oophorectomy following hysterectomy for benign conditions ($p=0.45$). Family history of ovarian, breast and colon cancer (94%) was the commonest factor followed by patient choice (48%), presence of ovarian cysts (45%), presence of endometriosis (37%), presence of peri-menopausal symptoms (35%), follicle stimulating hormone > 10 (17%) and other reasons (10%) were factors other than age influencing the decision of specialists, registrars and medical officers when performing prophylactic oophorectomy for benign disease, at the time of hysterectomy.

All the participants were aware of both local and international guidelines, namely American College of Obstetrics and Gynaecology (ACOG), Royal College of Obstetrics and Gynaecology (RCOG) and Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) were well known to the participants. Seventy six (41%) of the participants did not use any guidelines but used the age of the patient as well as a familial history of cancer as a guide to decide about surgery. Sixty nine (38%) were using international guidelines. Sixteen (9%) used departmental guidelines while 19 (10%) used their experience to decide. One hundred and fifty nine (85%) indicated that there is a need for local guidelines. Seventeen (10%) thought it was unnecessary. Nine (5%) gave no response.

CONCLUSION

Seventy six (41%) of the participants did not use any guidelines but used a history of cancer in the family and the age of the patient as a guide to decide about surgery. Sixty nine (38%) were using international guidelines. Sixteen (9%) used departmental guidelines while 19 (10%) used their experience to decide.

Factors that influenced specialists, medical officers and registrars to opt for bilateral oophorectomy, together with hysterectomy included familial history of breast, ovarian and colon cancer (94%) followed by patients choice (48%), presence of ovarian cysts (45%), presence of endometriosis (37%), presence of peri-menopausal symptoms (35%), follicle stimulating hormone > 10 (17%) and other reasons (10%).

There was no difference between specialists, registrars and medical officers with regards to age at which they recommended patients to have prophylactic oophorectomy following hysterectomy for benign conditions. As evident by the responses received in the questionnaire the majority of doctors (85%) felt that there was a need for guidelines to be set out in order to direct obstetricians and gynaecologists in making uniform decisions and to prevent unnecessary surgery.

This study was unable to adequately assess the difference in practice between the different groups (specialist, registrar, medical officer) as there was a limited number in participant responses.

1.1 Background and Literature

Bilateral oophorectomy is a procedure used electively in order to prevent ovarian and breast cancer in high risk women. This procedure is advocated in women regarded as having a higher potential for the development of breast, colon or ovarian cancer. There are few guidelines that stipulate exact criteria for oophorectomy at the time of surgery, especially in women with no familial risk for ovarian, breast and colon cancer. Kauff et al, indicated that when bilateral oophorectomy is performed in patients who have a familial predisposition to the disease there is a lower risk of breast cancer ^[1]. Women who undergo bilateral oophorectomy prior to onset of menopause lose their cyclic ovarian production of oestrogen and thus undergo a surgical menopause which results in many lifestyle changes. Hormone replacement therapy is thus advocated in these women in order to prevent subsequent decrease in sexual functioning, vasomotor symptoms, atherosclerosis, cardiac disease and bone changes.

Hormone replacement has been given to peri-menopausal and postmenopausal females to prevent the onset of osteoporosis and help alleviate climacteric symptoms. It has been found to prevent fractures and also increase bone density however the WHI study found that in older postmenopausal women using 0.625mg/day of conjugated equine oestrogens, there was a higher risk of developing blood clots. The oestrogen-plus-progestin sub-study of the WHI study reported a significant risk of stroke, pulmonary emboli, invasive breast cancer, myocardial infarction and DVT in postmenopausal females 50 years or older as well as a significant risk of dementia in postmenopausal females greater than 65 years of age using ‘PremPro’, which is composed of 0.625 mg of CEE together with 2.5 mg of medroxy-progesterone acetate^[2].

The three main controversies surrounding prophylactic oophorectomy are:

1. Should all females with a low risk for ovarian cancer be offered bilateral oophorectomy?
2. Should total hysterectomy accompany prophylactic oophorectomy when performed electively in high risk women?
3. What is the ideal age to perform prophylactic oophorectomy in high risk women?

A prospective cohort study from the Nurse's Health Study illustrated the degree of risk reduction of ovarian cancer when hysterectomy was performed together with bilateral salpingo- oophorectomy in the general population. The study included 29,380 women where hysterectomy was performed for non-malignant gynaecological disease, the average age was 43-47 years and the patients were followed for 24 years. The study showed that women with oophorectomy had significant reductions in ovarian cancer incidence (2 versus 42 cases per 100,000 person – years; HR 0.04, 95% CI 0.01-0.09) and ovarian cancer mortality (1 versus 14 deaths per 100,000 person- years; HR 0.06, 95% CI 0.02-0.21) as compared with patients with ovarian conservation ^[3].

This risk reduction was similar irrespective of the age at which hysterectomy was performed. The Women's Health Initiative Observational Study showed similar results, it included 25,448 patients where hysterectomy was performed for benign disease. Majority of women involved in the study were 49yrs or younger and it was found that the number needed to treat, in order to prevent one case of ovarian cancer was 323^[2]. Thoughtful consideration should be given to the younger females undergoing pelvic surgery for gynaecological conditions as prophylactic oophorectomy might not eliminate the patients risk for the development of intra-abdominal carcinomas example primary peritoneal carcinomas.

Gynaecologists have been plagued on whether to proceed with bilateral oophorectomy together with hysterectomy for benign gynaecological conditions. As yet there are still no protocols available to guide us in this decision making. In the 1987 Technical Bulletin, the American College of Obstetrics and Gynaecology (ACOG) recommended discussing prophylactic oophorectomy with women greater than the forty years old when advising a hysterectomy^[4].

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists published a statement as follows: “when hysterectomy is being performed in patients younger than 65 years for benign gynaecological disease, careful consideration should be made when bilateral oophorectomy is being performed.” Alison H Brand (2009) undertook a study in Australia and found that there was no agreement amongst gynaecology consultants and registrars in recommending the appropriate age at which to routinely perform prophylactic oophorectomies in females undergoing hysterectomy for non-malignant disease, except that , with increasing age there was a higher likelihood for oophorectomy^[5].

There is considerable variation in the decision for prophylactic oophorectomy as there are a few reliable studies to evaluate risks and benefits of the procedure. The benefits of oophorectomy are discussed as follows:

1.2 Benefits of Oophorectomy

1.2.1 Ovarian cancer prevention

Bilateral salpingo-oophorectomy was frequently performed at hysterectomies to decrease future risk of ovarian cancer and further reoperations for ovarian pathologies. It is estimated that a woman's lifetime risk of subsequent development of ovarian cancer is 1.4% in the United States of America however this risk estimation is dependent on ethnicity, number of pregnancies and the use of other oral contraceptive pill^[6]. The decision for prevention of ovarian cancer by performing BSO is controversial. Some physicians believe that approximately 1000 newly diagnosed patients with ovarian cancer can be prevented in the United States each year if bilateral oophorectomy was performed together with hysterectomy for women older than 40 years^[7]. In contrast to the beliefs of these physicians, there are others who have indicated that the rate of ovarian cancer after hysterectomy is low, with 2 women per 1000 experiencing a subsequent ovarian cancer after hysterectomy alone^[8].

Ovarian cancer is a fatal condition that is often overshadowed by the magnitude of breast and cervical cancer. Risk factors for the disease include: women who are nulliparous and infertile, women who have undergone conservative surgery for stage 1 ovarian cancer, a history of familial ovarian cancer and hereditary ovarian cancer syndrome. The factors that reduce the risk of ovarian cancer development are: Early use of oral contraceptive pills, first full term pregnancy at an early age, breast feeding and tubal ligation.

Considering the poor compliance of the oral contraceptive and low accuracy of screening tests in early recognition of ovarian cancer prophylactic oophorectomy is justified in premenopausal and postmenopausal women. In most countries the decision for prophylactic oophorectomies lies with the gynaecologist, hence the decision for our study arose from the need for proper guidelines to identify which patients were considered as appropriate for the necessary intervention. The American College of Obstetrics and Gynaecology have made the following recommendations: (The following recommendation is based on limited or inconsistent scientific evidence) Bilateral salpingo-oophorectomy should be offered to women with BRCA1 and BRCA2 mutations after completing childbearing^[4].

(The following recommendations are based primarily on consensus and expert opinion) Females with a family history which indicates BRCA mutations should have genetic counselling and BRCA testing. Females, who are at a higher risk of ovarian cancer, should have bilateral salpingo-oophorectomy with careful inspection of the peritoneal cavity, resection of the fallopian tubes, pelvic washings, and ovarian vessel ligation at the pelvic brim ^[4] .

Premenopausal women who are low risk with no genetic history of ovarian cancer should strongly be considered for ovarian preservation. Postmenopausal women have a risk of developing ovarian cancer therefore, oophorectomy and hysterectomy should be considered for these women. Women who are at higher risk for reoperation include those with pelvic inflammatory disease, endometriosis and chronic pelvic pain ; therefore careful consideration should be made in terms of risk of subsequent surgery if the ovaries are preserved against the benefit of ovarian retention in these patients ^[4] .

1.2.2 Reduced risk of future ovarian surgery

Women who have retained their ovaries are at risk for reoperation due to ovarian pathologies. The reported reoperation rate on retained ovaries ranges from 0.9 to 5.2% ^[9]. Ovarian residual syndrome appears in some women after hysterectomy in which one or both ovaries are conserved and is characterized by lower backache, lower abdominal pain and deep dyspareunia. This syndrome was more commonly seen in patients who underwent, hysterectomies at a younger age, this is thought to be due to the long postoperative ovarian function which results in greater opportunity for ovarian pathology.

Oophorectomies may play a role in preventing pelvic pain and ovarian cyst formation. In postmenopausal women with ovarian cysts the current recommendation is conservative management providing that the cyst size has not increased and the CA125 levels remain stationary ^[10] .

Dekel et al reported a study consisting of 2.561 women with hysterectomy and ovarian preservation that after 20yrs of follow-up only 2.8% required subsequent oophorectomy ^[9]. This therefore illustrates that the small percentage for repeat surgery does not warrant the deleterious effects of elective oophorectomy for majority of the women requiring a hysterectomy.

1.2.3 Prevention of breast cancer

Approximately 10% of all diagnosed cases of breast cancers are familial, and is identified in younger females with an increased risk of bilateral disease and strong association with BRCA1 and BRCA2 genes. Women who have mutations of BRCA1 have a lifetime breast cancer risk estimated at 54% and with BRCA2 mutations there is a risk of 23% ^[11]. The general population will have approximately 0.1-0.2% risk of BRCA mutations, while the rate is much higher in patients of Ashkenazi Jewish ancestry, which is approximately 2%. Patients who have positive tests for deleterious mutations can be considered for prophylactic surgery. Kauff et al conducted a prospective study in order to evaluate whether premenopausal prophylactic oophorectomy was efficient in reducing the incidence of breast cancer. In the study women who had not undergone mastectomy before enrolment were chosen for evaluation. In the surveillance group there were eight patients who had breast cancer versus 3 patients in the PO group ($P = .07$). The estimated amount of patients who were both free of ovarian and breast cancer at 5 years was substantially higher in the PO group ($P = .006$), with a hazard ratio of 0.25 for the development of either ovarian or breast cancer[1]. Breast cancer incidence is related to age, increasing at forty and fifty years of age and then continuing to rise but not as severely post menopause. Therefore endogenous sex hormones have been implicated in its development ^[12]. In patients who are 50yrs and younger undergoing oophorectomy a reduced risk in breast cancer has been reported. This reduced risk can be attributed to the decreased exposure of oestrogen. In patients older than 50yrs who have undergone an oophorectomy no benefit has been reported in breast cancer reduction. The NURSES HEALTH STUDY reported a reduction in breast cancer incidence in patients who had undergone an oophorectomy at 45yrs or less and not in other age groups (222 versus 315 cases per 100,000 person – years; HR 0.6, 95% CI 0.5-0.7)^[3].

1.3 Disadvantages of Oophorectomy

Premenopausal oophorectomy results in loss of cyclic ovarian hormone secretion, this results in both vasomotor symptoms (E.g. vaginal dryness) and other consequences of oestrogen deficiencies (e.g. hip fractures and osteoporosis). Oestrogen is important for bone remodelling, vascular integrity and for metabolism of lipids. Oestrogen is an important hormone, produced in the ovaries. It is present in its natural form as a steroid hormone and

occurs in three forms namely oestrone, oestradiol and oestriol. During the reproductive years of a female oestradiol is the predominant hormone while oestrone is the primary oestrogen hormone during the menopausal period. (FSH) stimulates the granulosa cells on the ovarian follicles to produce oestrogen. However oestrogen is also produced in secondary sites including liver, breast and fat cells. This secondary source of oestrogen is important for the menopausal female as ovaries decline in their function of producing oestrogen.

During puberty oestrogen plays a vital role in secondary sexual characteristics. In the adult female it enhances growth of the endometrium, vaginal lubrication, ovulation and plays an important role in the female sex drive. Oestrogen is also important for the growth of new bone and reduces bone resorption. It has also been noted to reduce fat deposition and increase (HDL). Oestrogen is vital for mental health, with low levels of oestrogen correlating to low moods. Douma et al found that oestrogen played a vital role in stabilizing depressive symptoms in premenopausal and postmenopausal females^[13].

Thus the positive effects of physiological oestrogen and the prevention of an early surgical menopause remains a strong argument for ovarian conservation.

1.3.1 Cardiovascular disease

Prophylactic oophorectomy performed during hysterectomy for benign conditions has been associated with loss of ovarian sex steroid hormones as a result of the surgical menopause that ensues. Natural menopause usually occurs around the ages of 45 to 55 years it is a gradual process which is associated with menstrual irregularities. In surgical menopause patients are usually younger and experience effects of oestrogen deficiency suddenly and they are usually noted soon after removal of the ovaries. Long term effects of oestrogen deficiency can lead to increased risk of cardiovascular disease^[14].

Menopausal women have been noted to have higher levels of serum lipids and plasma fibrinogen profiles which predispose them to cardiovascular disease. Low levels of endogenous oestrogens during the menopausal period causes higher levels of low – density lipoproteins which together with smoking and hypertension greatly increase the risk of cardiovascular disease. Several studies have shown an association of prophylactic oophorectomy with coronary heart disease^[15, 16]. The Nurse's Health Study found a

significant increase in coronary heart disease in patients who underwent oophorectomy (207 versus 163 per 100,000 person years; HR 1.17, 95% CI 1.02-1.35) ^[3].

This can be expressed as one extra death from coronary heart disease for every 130 women who have undergone bilateral oophorectomy. However the risk of developing cardiovascular disease is controversial and has been based on observational data only. A subset analysis found a significant increase in cardiac disease in women younger than 40yrs at the time of oophorectomy ^[16].

In contrast the Women's Health Initiative Observational Study found no significant association between oophorectomy and coronary heart disease (380 versus 353 per 100,000 person-years; HR 1.00, 0.85-1.18). Metabolic diseases (e.g. type 2 diabetes) and dyslipidaemias have been noted to be more prevalent in postmenopausal than in premenopausal females. These conditions are important risk factors for cardiovascular disease.

1.3.2 Osteoporosis/hip fractures

Osteoporosis is a skeletal disease characterised by low bone mass, changes in the micro-architecture and breakdown in the remodelling of the bone. Oestrogen is essential for new bone formation. Both osteoblasts and osteoclasts have oestrogen receptors. Oestrogen inhibits lysosomal enzyme production thereby decreasing bone resorption and causes osteoblasts to produce cytokines which inhibit osteoclast activity. Osteoporosis is commonly seen affecting cancellous bone with increased fractures noted over the vertebrae and proximal femur.

Oophorectomy is associated with a significant risk for the formation of osteoporosis, especially if it occurs before the age of 45yrs. Early menopause and oophorectomies have been associated with lower bone density which is associated with a higher fracture rate ^[17]. Oestrogens and androgens play a role as inhibitors of bone resorption and surgical menopause has been associated with decreased levels of endogenous oestrogens and androgens. One study which evaluated 340 women where a prophylactic oophorectomy was performed at a median age of 62yrs, over a period of 16 years, reported a 54% higher risk of osteoporotic fractures than females who retained their ovaries ^[18]. In patients greater than 60 years of age where oophorectomy had been performed, there was a two-fold risk of death

following a low-trauma hip fracture, compared to women who had intact ovaries (odds ratio [OR], 2.18; 95% CI, 2.03–2.32) ^[18].

1.3.3 Cognitive function

Dementia and depression have been associated with oophorectomy. The Mayo Clinic Cohort Study of Oophorectomy and Aging found that when oophorectomy was performed prior to the start of menopause there was an increased risk for the development of dementia, anxiety, depression and parkinsonism. The Women's Health Initiative study found that patients older than 65 years who were either treated with only oestrogen or a combination of oestrogen and progestin, had a higher risk for cognitive impairment and dementia ^[19]. The findings of the study show us that oestrogen might have a protective function if it is administered soon after menopause and might be harmful if administered many years after menopause ^[20]. Multiple studies have shown that endogenous ovarian hormones are important for brain integrity ^[20, 21]. Clinical studies have shown a higher incidence of depression in surgical menopause than in natural menopause ^{[22] [23] [24]}.

1.3.4 Mental Health and Sexual Function

Endogenous androgens produced in the ovarian stroma have been noted to play a key role in the female sexual drive. Oophorectomies in premenopausal females result in decreased endogenous androgens this has been suggested as a causal factor in decreased libido. Studies have shown that women who have had BSO reported sexual dysfunction than women with retained ovaries, and their symptoms have not improved with oestrogen therapy ^[25, 26]. Madalinska and colleagues found that in females who underwent prophylactic oophorectomy there was a higher risk for decreased sexual satisfaction and dyspareunia than with females who underwent only medical surveillance ^[27].

In the premenopausal women oophorectomy causes a sudden loss of oestrogen and over time, there is vaginal dryness, loss of orgasm, decreased libido and sexual dysfunction. This is associated with feelings of decreased self-worth and a negative image. In a prospective study involving 101 women, females who had oophorectomy together with hysterectomy were found to be more anxious and depressed and had a lower positive well-being than females who underwent hysterectomy alone ^[25]. A study involving European patients with low risk for cancer found that females who underwent BSO had a double risk of developing

hypoactive sexual desire syndrome as compared to patients who were premenopausal or developed natural menopause ^[28].

1.4 Statement of the Problem

There are few guidelines that stipulate exact criteria for oophorectomy at the time of surgery, especially in females with no familial risk for ovarian, breast and colon cancer. In most countries the decision for prophylactic oophorectomies lies with the gynaecologist, hence the decision for our study arose from the need for proper guidelines to identify which patients were considered as appropriate for the necessary intervention.

Chapter Two - Methodology

2.1 Objectives

1. To identify local practice of prophylactic oophorectomy at the time of hysterectomy.
2. To identify which conditions would favour ovarian preservation versus those which would support oophorectomy.
3. To identify which guidelines gynaecologists, registrars and medical officers practice.
4. To assess the need for local guidelines on prophylactic oophorectomy at the time of hysterectomy for benign disease.
5. To assess if differences in practices exist between different groups (public, private consultants, senior registrars, medical officers, male and females).

2.2 Research design

This was a descriptive study using questionnaire surveys.

2.3 Study population

Medical doctors with interest in obstetrics and gynaecology were approached at the SASOG (South African Society of Obstetricians and Gynaecologists) May 2012 conference.

2.4 Sampling and Data collection

Since this is a descriptive study, the power of the study is not considered in sample size calculation. Rather the precision that the sample size will provide to estimate a given parameter of the population. Since many parameters are being investigated, it was decided the sample size should be decided on logistical and time constraints rather than statistical validity.

2.5 Inclusion and exclusion criteria

2.5.1 Inclusion criteria

Gynaecology registrars, medical officers and gynaecologists who attended the SASOG meeting in Drakensberg May 2012.

2.5.2 Exclusion criteria

Nonmedical personnel and those not involved in obstetrics and gynaecology.

2.6 Data collection and methods

Descriptive study that was presented as a questionnaire to medical doctors practising in obstetrics and gynaecology at the SASOG conference in Drakensberg (May 2012)

2.7 Data analysis

The data collected will be captured and subsequently analysed using the Statistical Package for Social Sciences (SPSS version 19). Descriptive statistics such as mean, standard deviation, frequencies and percentages will be used to summarize results. Pearson Chi-square test or Fisher's exact test will be used to test for association level of experience and current practice. Two independent samples test or Mann Whitney test will be used to test if there is any relationship between current practice and age of the practitioner.

2.8 Ethical consideration

The study was approved by the Biomedical Research Ethics and Postgraduate Committees of the University of KwaZulu Natal. This was a descriptive study where patient's confidentiality was maintained, case numbers instead of patients names were used as identification. All principles of the Declaration of Helsinki were upheld. Ethics number REF: BE 087/12 (Appendices 2 and 3 for BREC and postgraduate approval, respectively).

Chapter Three - Results

3.1 Age

One hundred and eighty five participants took part in this questionnaire based study. The mean (range) age of the participants was 46 ± 8.2 (range: 28-75) years. The participants were either specialist (n=147), registrar (n=35) or medical officer (n=3). The mean (SD) age of the specialists was 47.9 ± 14.2 years and the mean (range) number of months since being qualified as was a specialist was 16 (1-146) months. The mean (SD) of the registrars was 51.6 ± 14.7 years and the mean (range) number of years in training 3 (1-5) years. The mean (SD) age of the medical officers was 48.3 ± 2.9 years. There was no difference in age between the participants ($p=0.3$). The age groups of the participants were as follows: 20-30 (n=6; 3%); 31- 40 (n= 60; 32%); 41-50 (n=58; 31%); 51-60 (n=42; 23%) and >60 (n=19; 10%) and is depicted graphically in Figure 1.

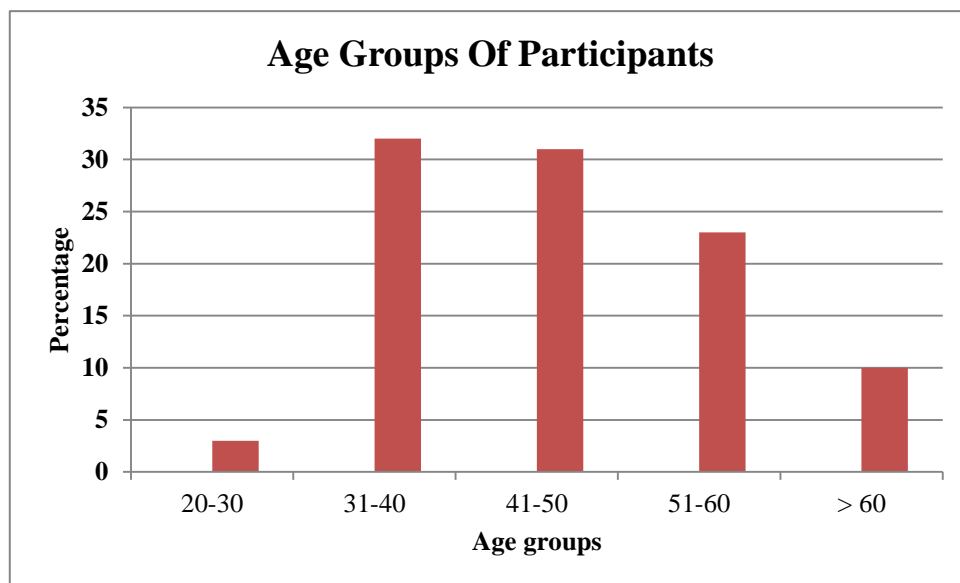


Figure 1: Age of Participants

3.2 Sex

One hundred and twelve (71%) of participants were male and the remaining 73 (29%) were females. The sex distributions of the participants are shown in Figure 2.

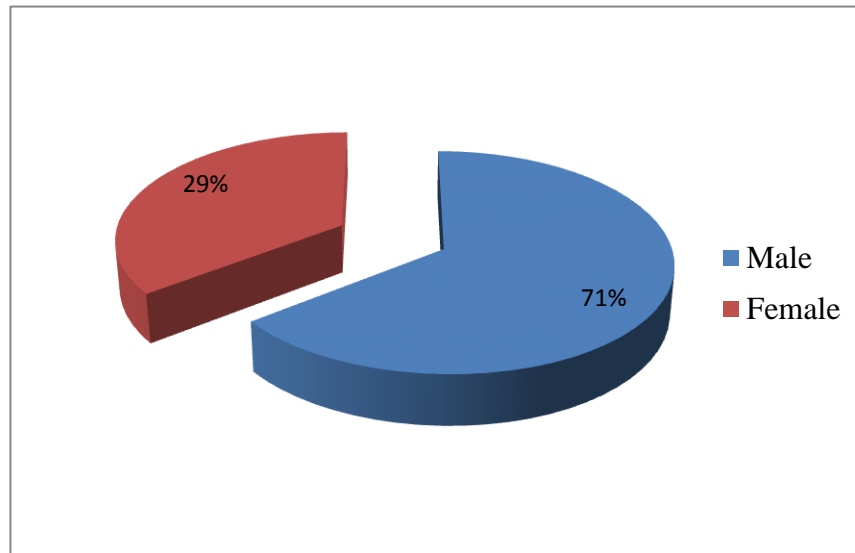


Figure 2: Sex of participants

3.3 Province of medical practice

Thirty six (19%) of the participants practiced in Gauteng followed by Western Province 22 (12%), KwaZulu Natal 12 (6%), Orange Free State 9 (5%), Mpumalanga 6 (3%), Northern Province 4 (2%), Eastern Province, Northern Cape and others (USA (n=2) and Nairobi) 3(2%) and North West Province 2 (1%).

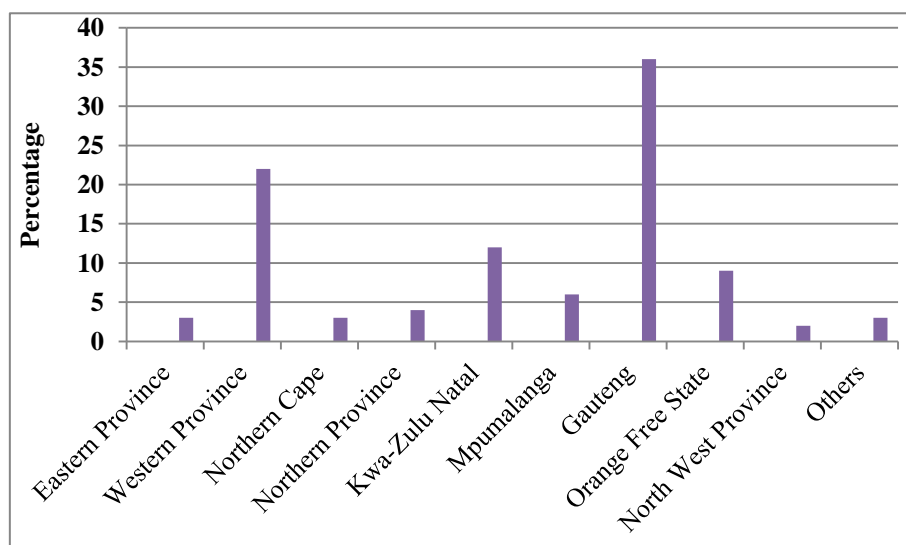


Figure: 3. Provinces where participants are practicing

3.4 Type of practice

Eighty eight (48%) were practicing in private, 71 (38%) were practicing in the public sector while 36 (14%) were practicing in both private and public sector. Where the participants are practicing is depicted in Figure 4.

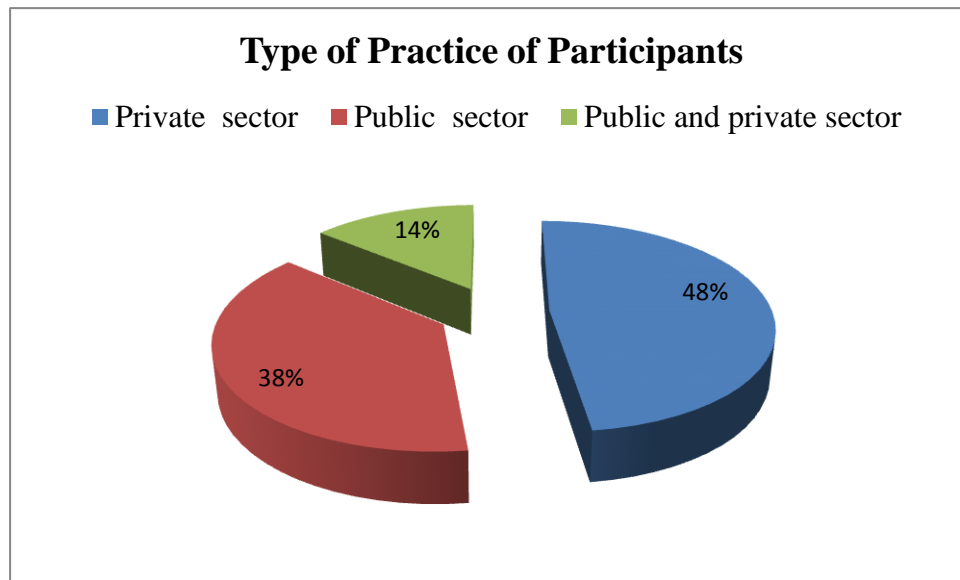


Figure 4: Type of practice

3.5 Level of experience

Among the participants there were 147 (79%) specialist, 35 (19%) registrars and 3 (2%) were medical officers. The level of experience of the participants are shown in Figure 5

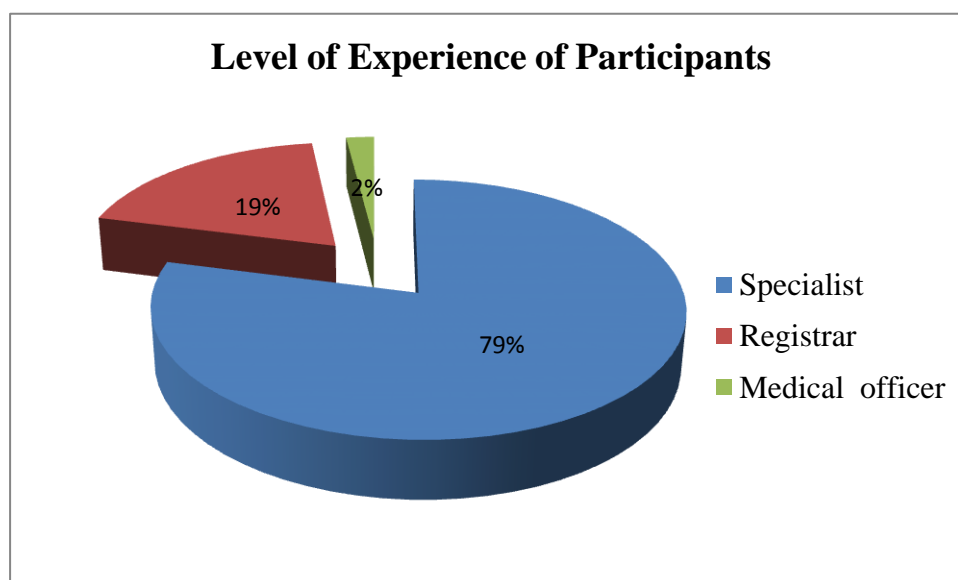


Figure 5: Level of experience

3.6 Place of postgraduate training

Majority of the participants did their postgraduate training in University of Stellenbosch (n=41; 22%); followed by 37 (20%) at University of Pretoria; 30 (16%) at University of Witwatersrand; 25 (14%) at University of Free State and University of KwaZulu Natal; 11 (6%) at University of Cape Town; 7 (4%) at Medunsa; 3 (2%) Limpopo University, Walter Sisulu University and Others (USA (n=2); Nairobi (n=3)).

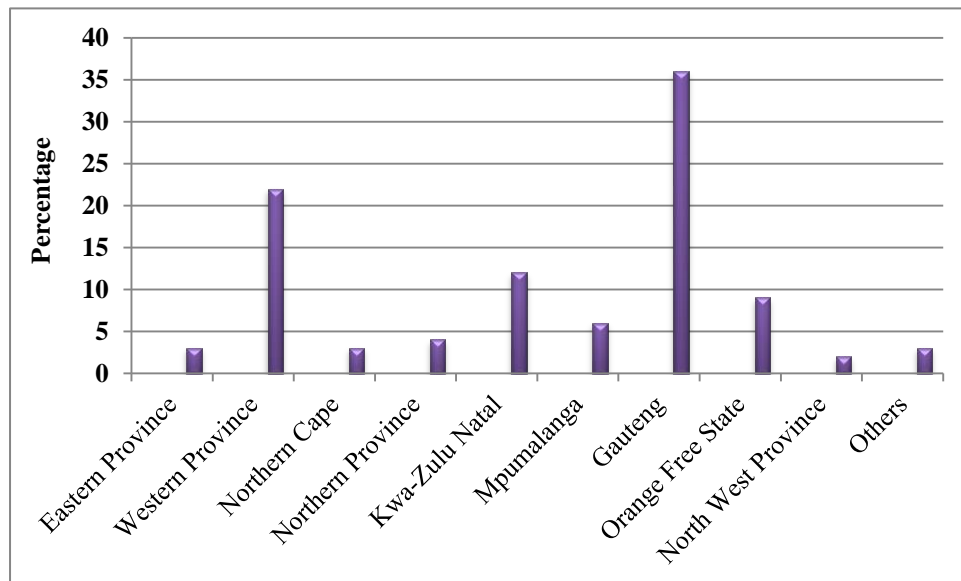


Figure 6: Place of postgraduate training of participants

3.7 Year of graduation

Majority (90%) of the participants graduated between the years 1980-2000. The year of graduation of the participants are listed in Table 1.

Table 1: Year of graduation of participants

Year	Number	Percentage
1930s	1	1
1960s	2	1
1970s	15	8
1980s	37	20
1990s	55	30
2000	75	40

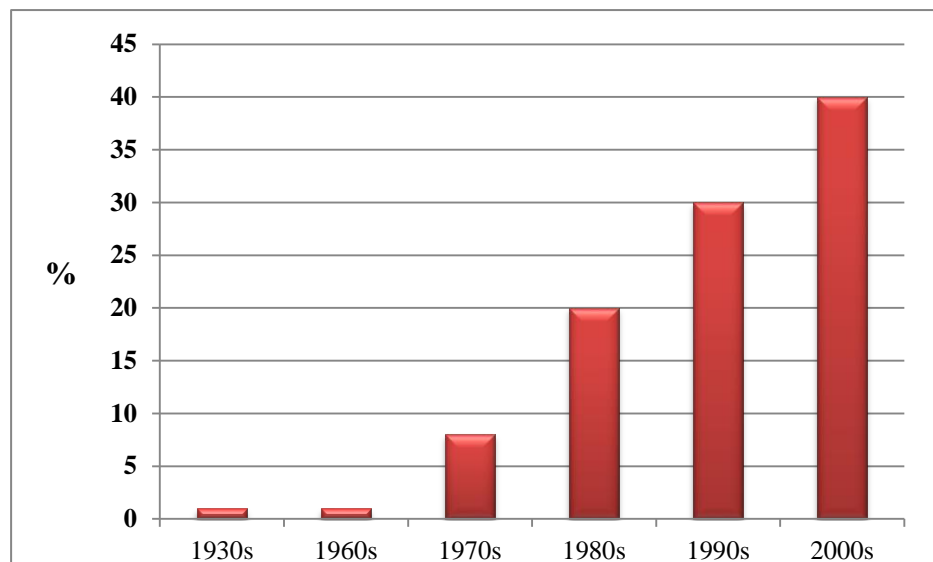


Figure 7: Shows year of graduation

3.8 At what age do you recommend your patients to have prophylactic oophorectomy following hysterectomy for benign conditions?

The mean (SD + range) age at which specialists, registrars and medical officers recommend patients to have prophylactic oophorectomy following hysterectomy for benign conditions was 52.18 ± 4.7 (35-65); 54.49 ± 5.3 and 55 ± 3.9 years respectively. There was no difference between specialists, registrars and medical officers with regards to age at they recommend patients to have prophylactic oophorectomy following hysterectomy for benign conditions ($p=0.45$).

3.9 Which factors would strongly influence your decision other than age to do prophylactic oophorectomy at the time of hysterectomy for benign disease?

Table 2 depicts factors other than age influencing the decision of specialists, registrars and medical officers when performing bilateral oophorectomy at hysterectomy for non-malignant disease. Familial history of ovarian, breast or colon cancer (94%) was the commonest factor followed by patient's choice (48%), presence of ovarian cysts (45%), presence of endometriosis (37%), presence of peri-menopausal symptoms (35%), follicle stimulating hormone > 10 (17%) and other reasons (10%). A number of participants listed multiple factors of which familial history of ovarian, breast or colon cancer, presence of ovarian cysts and presence of endometriosis was most common.

Table 2: Factors influencing decision other than age for prophylactic oophorectomy at the time of hysterectomy for benign disease

Variable	Number	Percentage
Familial history of breast/ovarian/colon cancer	174	94
Follicle stimulating hormone > 10	30	17
Presence of peri-menopausal symptoms	64	35
Presence of ovarian cysts	82	45
Presence of endometriosis	67	37
Patience choice	88	48
Any other reasons	17	10

3.10 Are you aware about the WHI study on HRT?

One hundred and eighty (97%) of the participants were aware of WHI study on HRT. Five (3%) did not know about the WHI study on HRT

3.11 Has the results of WHI study on HRT changed your practice of prophylactic oophorectomy following hysterectomy for benign conditions?

Two hundred and two (81%) of the participants indicated that they benefitted after reading the results of the WHI study on HRT and subsequently changed their practice of prophylactic oophorectomy following hysterectomy for benign conditions. In 35 (14%) participants, the results of the WHI study on HRT did not affect their practice. A very small percentage (6%) of the academics did not respond to this question.

In 129 (64%) of the 202 participants stated that after reading the WHI results they would delay the unnecessary prescribing and the use of HRT. Sixty (30%) of the 202 participants stated the WHI results prevented them from doing unnecessary surgery. The analysis of data of this question is shown in Table 3 and is illustrated graphically in Figure 8.

Table 3: Outcomes of the results based on the WHI study on HRT

Variable	Number	%
Delay in the use of HRT	129	64
Prevent unnecessary surgery	60	30
Others	13	6

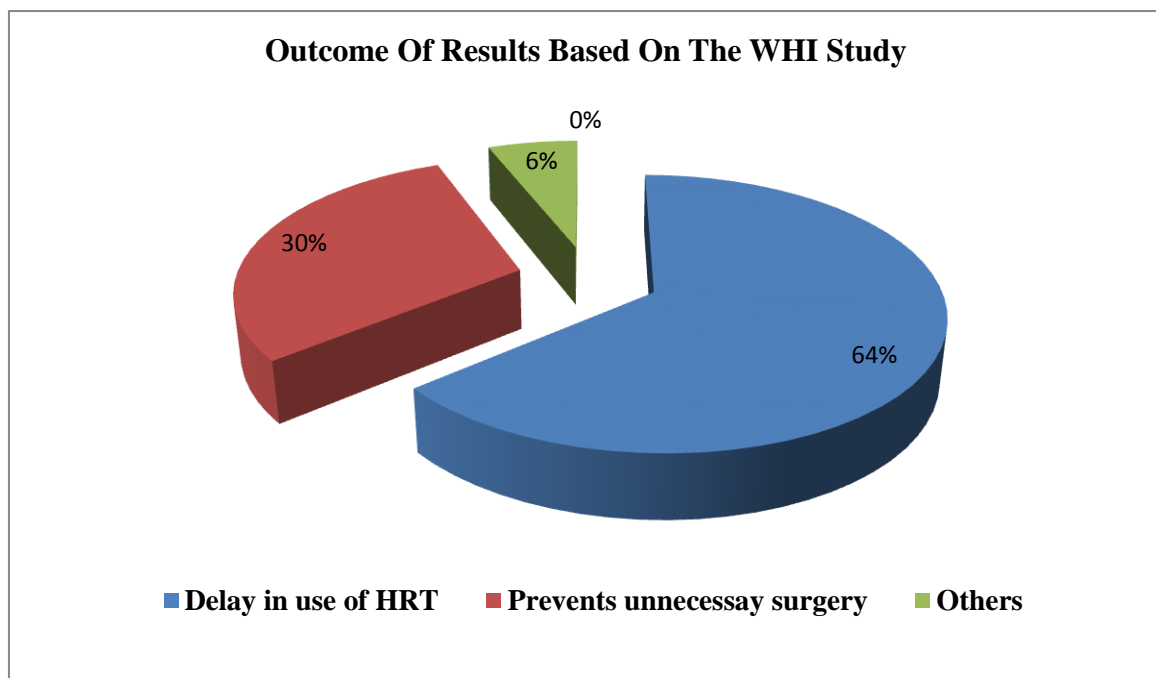


Figure 8: Outcomes of results based on WHI study

3.12 Aware of current guidelines (local/international)

All the participants were aware of both local and international guidelines. International guidelines namely American College of Obstetrics and Gynaecology (ACOG), Royal College of Obstetrics and Gynaecology (RCOG) and Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) were well known to the participants. Source of guidelines are shown in Figure 9.

Table 4: Guidelines known by participants

Guidelines known	Number	%
ACOG	70	38
RCOG	43	23
RANZCOG	31	17
Journals/Courses/Lectures	16	9
Departmental Guidelines	16	9
Others	9	5

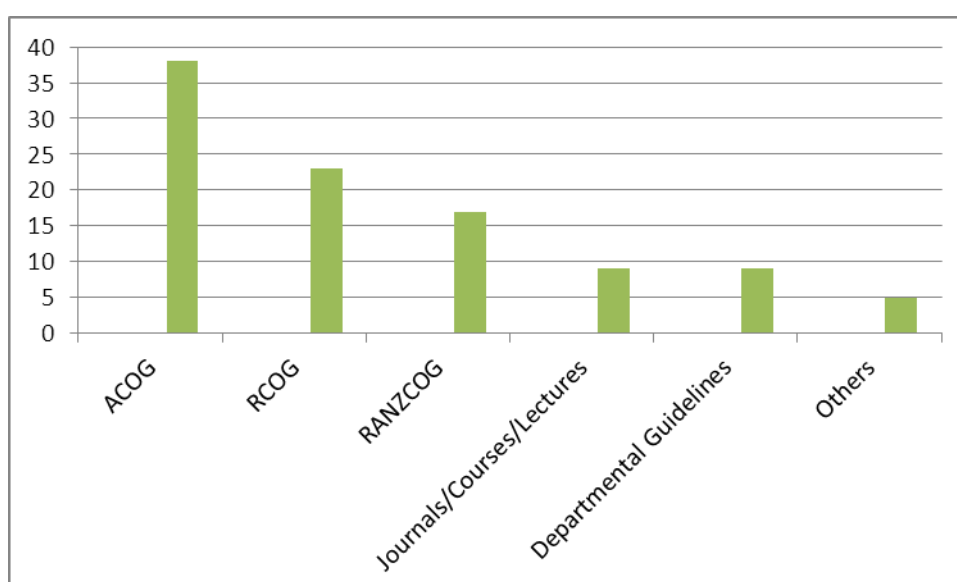


Figure 9: Participants awareness of guidelines

Chapter Four - Discussion

Prophylactic oophorectomy was generally performed together with an elective hysterectomy for women greater than the age of 50 years as it was believed that this would decrease the patient's risk of subsequent development of ovarian cysts, carcinomas and repeat surgeries.

The decision to perform oophorectomy in conjunction with hysterectomy for benign conditions is often made by the attending gynaecologist. The results from this study showed that prophylactic oophorectomy was being performed on patients greater than 50 years of age. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists published a statement as follows: "when hysterectomy is performed in patients less than 65 years for benign gynaecological disease careful consideration should be made when bilateral oophorectomy is being performed."^[5] Prophylactic oophorectomy performed in the premenopausal female has been associated with a higher incidence of osteoporosis and hip fracture^[29] cognitive impairment^[30], and cardiovascular mortality^[31].

Patients who developed surgical menopause were started on HRT to help relieve vasomotor symptoms such as hot flushes. The WHI Study however indicated that women who received hormone replacement had a significant risk of developing cardiac disease and strokes. 81% of the participants from this study stated that they had benefitted from the WHI study and 64% had delayed the premature administration of HRT. A separate analysis in the Nurse's Health Study analysed women who never utilized postmenopausal HRT. It showed that women who had a bilateral oophorectomy had a higher risk of stroke (HR, 1.85; 95% CI, 1.09, 3.16) than women who had conserved their ovaries. Amongst the women where oophorectomy was performed before 50 years and were HRT was not utilized, the risk of CAD was higher (HR, 1.98; 95% CI, 1.18, 3.32)^[14]. The rates of usage of oestrogen continue to decline amongst women with bilateral oophorectomy^[31], despite the positive benefits of the hormone in patients who have undergone BSO. After 6 months following the introduction of the Women's Health Initiative study on oestrogen-progestin therapy, it was found that oestrogen replacement reduced from 12.6% to 9.1%^[31]. The results from this study state that 97% of participants were aware of the WHI study and that 64% would delay the unnecessary administration of HRT to patients following outcomes yielded from the study (table 3).

Participants in this study were aware about local and international guidelines available (table 4) however 41% did not utilize the guidelines to make informed decisions. Instead they used the family history of cancer and the age of the patient as a guide to decide on surgery, 38% used international guidelines, 9% utilized departmental guidelines and 10% used their own discretion and experience to make a decision. Factors that strongly influenced the decision for prophylactic oophorectomy other than age were as follows: family history of ovarian breast and colon cancer (94%) followed by patient's choice (48%), presence of ovarian cysts (45%), presence of endometriosis (37%), presence of perimenopausal symptoms (35%), follicle stimulating hormone > 10 (17%) and other reasons (10%) (table2). A number of participants listed multiple factors of which familial history of ovarian, breast and colon cancer, presence of ovarian cysts and presence of endometriosis being strong motivation for BSO. The participants in this study favoured oophorectomy especially with regards to age greater than 50 years with a familial history of cancer and patients who requested removal of the ovaries.

Conservative management in patients greater than 50 years was not done as patients requested surgical intervention as to prevent cancer and future surgical interventions. The majority of the participants (85%) indicated the need for local guidelines to allow for uniformity of diagnosis, clear decision making, to guide practices, and to prevent medico-legal issues and unnecessary surgery. There was no difference between specialists, registrars and medical officers with regards to age at which they recommended patients to have prophylactic oophorectomy, when hysterectomy was performed for benign conditions.

Prophylactic oophorectomy has been shown to be beneficial in patients with BRCA1 and BRCA2 genes in order to prevent the development of breast and ovarian cancer however in low risk females with no family history of cancer it has been linked with a high risk of morbidity and mortality. The dilemma at present is that:

1. Should all women with low risk for ovarian cancer be offered prophylactic oophorectomy?
2. What is the ideal age to perform bilateral oophorectomy in high risk women?

The results from this study identify prophylactic oophorectomy as the treatment of choice for patients greater than the age of 50 years with benign gynaecological conditions. This

practice is not in keeping with the RANZOG statement on exercising caution in performing bilateral oophorectomy in patients younger than 65yrs with benign disease. In the United States of America, 40% of hysterectomies for non-malignant conditions are accompanied with BSO when performed among patients aged 40–44 years; in 60%, among patients aged 45–50 years; and in 78%, among patients aged 50–55 years^[32]. The recommended age of prophylactic oophorectomy of 50years as recommended by this study is also partially supported by two studies conducted in the United Kingdom by Jacobs et al^[33] and in Italy by Mezzapane et al^[34] which reported approximately 20% of gynaecologists who routinely perform prophylactic oophorectomies for patients aging between 45-50 years. 48% of participants felt that patient choice was a strong reason to decide on surgery and not conservative management. This decision should however only be done with patients assessed on an individual basis with their gynaecologist. Careful attention should be made especially to benefits and disadvantages of prophylactic oophorectomy for benign conditions.

Majority of the participants in this study were males (71%), specialist gynaecologists (79%) and working in the private sector. However with regards to decision for prophylactic oophorectomy, there was uniform consensus amongst participants. There was a discrepancy in the ratio of male to female participants, therefore this study was unable to determine whether a difference of practice exists with the different sexes. The results from this study show that irrespective of the years of experience of the gynaecologist (figure 5), or university in which post-graduate teaching was accomplished the participants, still performed prophylactic oophorectomy in patients older than 50 years.

The recommendation from this study is that patients who are more than 50 years should have an oophorectomy together with hysterectomy for benign gynaecological conditions. This is strongly supported especially in patients who have a family history of either breast and/or ovarian cancer. This study also recommends that guidelines be made available in order to assist the gynaecologist as well as the patient in making an informed decision with regards to surgery.

4.1 Limitations of the study

The study was conducted at an Obstetrics and Gynaecology conference with a select amount of participants as such a limited number of doctors were present and majority of the medical doctors were specialists from the private sector.

4.2 Conclusion and Recommendations

As evident by the responses received in the questionnaire the majority of doctors (85%) felt that there was a need for guidelines to be set out in order to direct obstetricians and gynaecologists in making uniform decisions and to prevent unnecessary surgery. Seventy six (41%) of the participants did not use any guidelines but used the familial history of cancer and the age of the patient as a guide to decide about surgery. Sixty nine (38%) were using international guidelines. Sixteen (9%) used departmental guidelines while 19 (10%) used their experience to decide.

Factors that influenced specialists, medical officers and registrars to opt for prophylactic oophorectomy at the time of hysterectomy included family history of ovarian/breast/colon cancer (94%) followed by patients choice (48%), presence of ovarian cysts (45%), presence of endometriosis (37%), presence of peri-menopausal symptoms (35%), follicle stimulating hormone > 10 (17%) and other reasons (10%). There was no difference between specialists, registrars and medical officers with regards to age of more than 50 years at which they recommended patients to have prophylactic oophorectomy following hysterectomy for benign conditions.

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Appendix 1



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31 May 2012

Dr R Vatharajh
13 Berriedales
30 Berriedale Road
DURBAN
4001

Dear Dr Vatharajh

PROTOCOL: Prophylactic oophorectomy at the time of hysterectomy for benign disease.
REF: BE087/12

The Biomedical Research Ethics Committee (BREC) has considered the abovementioned application.

The study was provisionally approved by a quorate meeting of BREC on 30 April 2012 pending appropriate responses to queries raised. Your responses dated 30 April 2012 to queries raised have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 31 May 2012.

This approval is valid for one year from 31 May 2012. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC

Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/ResearchEthics11415.aspx>.
BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely



PROFESSOR V RAMBIRITCH
Vice-Chair: Biomedical Research Ethics Committee

Appendix 2



10 May 2012

Dr R Gangaram
Department of Obstetrics and Gynaecology
School of Clinical Medicine

Dear Dr Gangaram

PROTOCOL: "Prophylactic oophorectomy at the time of hysterectomy for benign disease." Student: R Vatharajh,
student number: 9500003. (Obstetrics and Gynaecology)

I am pleased to inform you that the abovementioned study has been approved.

Please note:

- The Academic Leader: Research must review any changes made to this study.
- The study may not begin without the approval of the Biomedical Research Ethics Committee.

May I take this opportunity to wish the student every success with the study.

Yours sincerely

pp: Professor R Hift
Dean: School of Clinical Medicine

CC: Dr R Vatharajh

Biomedical Research Ethics Committee
Westville Campus

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Appendix 3

Study: Prophylactic oophorectomy at the time of hysterectomy for benign disease

Questionnaire number:

A) Personal Details (tick appropriate box)

1) Age

--

2) Sex

Male	female
------	--------

3) Province of medical practice

Eastern Cape	Mpumalanga
Western Cape	Gauteng
Northern Cape	Free State
Northern Province	North West
Kwazulu Natal	Other

4) Type of Practice

Private practise	
Public sectors	
Public and private sector	

5) Level of experience

Specialist	
Registrar	
Medical officer	

6) Place of post graduate training (if applicable)

University of Kwa-Zulu Natal	
University of Pretoria	
University of Cape Town	
University of Bloemfontein	
University of Stellenbosch	
Walter Sisulu University	
Limpopo University	
Medical University of South Africa	
Other	

7) Year of graduation

--

B) Level of experience (tick appropriate box)

8) If specialist

Number of years of qualification as specialist.	
---	--

9) If Registrar

Number of years of training.	
------------------------------	--

10) If Medical Officer

Number of years of training	
-----------------------------	--

a) Have you previously trained as a registrar in obstetrics and gynaecology

Yes	No
-----	----

b) If yes, state the number of years

--

C) Factors influencing decision for prophylactic oophorectomy

11) At what age do you recommend your patients to have prophylactic oophorectomy following hysterectomy for benign conditions :

--

12) Which factors listed below would strongly influence your decision other than age to do prophylactic oophorectomy at the time of hysterectomy for benign disease:

family history of ovarian/breast/colon cancer	
follicle stimulating hormone > 10	
presence of peri-menopausal symptoms	
presence of ovarian cysts	
presence of endometriosis	
patient choice	
other reason	

13) Are you aware about the Women's Health Initiative (WHI) study on hormone replacement therapy (HRT)?

Yes	No
-----	----

14) Has the results of WHI study on HRT changed your practice of prophylactic oophorectomy following hysterectomy for benign conditions

Yes	No
-----	----

15) If yes, how?

D) Guidelines (tick appropriate box)

16) Are you aware of current guidelines (local / international) for prophylactic oophorectomy at the time of hysterectomy for benign conditions?

yes	no
-----	----

17) If yes, please state source of guideline

- 18) Do you think there is a need for local guidelines on prophylactic oophorectomy at the time of hysterectomy for benign conditions? If yes, please state reason.

- 19) What guidelines are you currently using in determining which patients are suitable for prophylactic oophorectomy?

Appendix 4



UNIVERSITY OF
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Department of Obstetrics & Gynaecology
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26 March 2013

Mrs Vorster
College of Medicine of South Africa
Johannesburg
South Africa

Dear Mrs Vorster

Re: Dr R Vatharajh for FCOG(SA) Part 11

Please find attached the dissertation: "Prophylactic Oophorectomy at the time of hysterectomy for benign disease – current practice and need for guidelines."
This has been carried out by Dr R Vatharajh during her registrar training.

Yours sincerely

Prof JS Bagratee
Professor and Head